

LISTING OF THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Previously Presented) A process for detecting or determining a C-peptide-containing impurity in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps:
 - (a) preparing a sample of recombinantly produced human insulin or a derivative thereof;
 - (b) mixing the samples with dilution buffer;
 - (c) adding a tracer to mixture (b);
 - (d) adding antibody specific for the C-peptide impurity to mixture (c);
 - (e) adding a C-peptide second antibody bead having at least one label to mixture (d); and
 - (f) detecting or determining the presence of the C-peptide-containing impurity.
2. (Original) The process according to claim 1, wherein the C-peptide-containing impurity is C-peptide, preproinsulin or a derivative thereof, or a C-peptide containing insulin or a derivative thereof.
3. (Original) The process according to claim 1, wherein the process is performed at a pH of about 8.5 to about 9.0.

4. (Original) The process according to claim 1, wherein the antibody specific for the C-peptide recognizes monkey C-peptide.
5. (Canceled)
6. (Currently Amended) The process according to claim 1, wherein the antibody specific for the C-peptide impurity additionally recognizes at least one ~~model compound~~ compound chosen from preproinsulin, reduced human insulin, alkylated human insulin, human insulin cleaved with endoproteinase, Lys(B3)-Glu(B29)-human insulin C-peptide, and Lys(B3)-Glu(B29)-human insulin preproinsulin.
7. (Previously Presented) The process according to claim 1, wherein the antibody specific for the C-peptide impurity recognizes both C-peptide and preproinsulin with nearly the same affinity.
8. (Previously Presented) The process according to claim 1, wherein the tracer is chemiluminescent.
9. (Previously Presented) The process according to claim 8, wherein the tracer comprises an acridinium ester moiety.

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10. (Previously Presented) The process according to claim 1, wherein the presence of about 1 mg/mL human insulin does not interfere with the binding of the antibody specific for the C-peptide impurity.
11. (Previously Presented) The process according to claim 1, wherein the antibody specific for the C-peptide impurity is obtained by immunizing a mammal with a purified insulin C-peptide.
12. (Previously Presented) The process according to claim 11, wherein the mammal is a sheep.
13. (Previously Presented) The process according to claim 11, wherein the purified insulin C-peptide is monkey C-peptide.
14. (Previously Presented) The process according to claim 11, wherein the purified insulin C-peptide is human C-peptide.